

REMARKS

Election/Restrictions

Claims 4, 5, 16 and 40-62 have been withdrawn from consideration as being drawn to a non-elected species of the invention. The Applicant has cancelled claims 40-62 without prejudice for possible submission in a continuing application. The Applicant has chosen to maintain the withdrawn claims 4, 5 and 16 in the pending application for possible reinstatement upon the allowance of one or more generic base claims.

Claim Objections

Claim 27 has been objected to for an antecedent basis informality. The Applicant has appropriately amended claim 27 to address the informality and withdrawal of the object to claim 27 is respectfully requested.

Claim Rejections – 35 USC §102

Claims 1-3, 6-15, 19-23, 25-31, 33 and 35-39 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,375,683 to Crozet et al. Claims 1, 9, 10-12, 25, 29-31 and 35-37 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,401,112 to Rezaian. Claims 1-3, 6-12, 23-31 and 33-38 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0107519 to Dixon et al. Claims 1, 9-12, 19, 20, 24, 25, 29-31 and 34-38 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,892,545 to Day et al. Claims 1, 9-12, 24, 25, 29-31 and 34-38 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,611,581 to Steffee. Claims 1-3, 6-12, 15, 17-23, 25-32 and 35-40 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,683,394 to Rinner.

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Independent Claim 1 and Dependent Claims 8-16, 19-24 and 63-71

The Applicant has amended independent claim 1 to recite, among other elements and features, a spinal implant comprising “an intervertebral fusion device including one or more openings configured to promote fusion with the adjacent vertebral bodies” and having a first transverse dimension and a second transverse dimension greater than the first transverse and corresponding to a select height of the intervertebral space, an elongate member sized to span the intervertebral space, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height” as the spinal implant is transitioned from the first transverse dimension to the second transverse dimension to provide controlled compression of the spinal implant. The amendments incorporated into independent claim 1 are supported, for example, by paragraphs [0015] and [0020], as-filed claims 17 and 24, and Figures 1-4.

With regard to the Crozet, Rezaian, and Day references, each of these references discloses an expandable spacer device. Additionally, Steffee discloses an expandable bone anchor device configured for expansion within vertebral bone, and Dixon discloses a distractor/spreader instrument for distracting adjacent vertebrae. Notably, none of these references disclose or even suggest “an intervertebral fusion device including one or more openings configured to promote fusion with the adjacent vertebral bodies”, as now recited in independent claim 1. Indeed, none of the devices disclosed in these references comprise “an intervertebral fusion device”, much less an intervertebral fusion device “including one or more openings configured to promote fusion with the adjacent vertebral bodies”. This distinction was apparently appreciated by the Examiner in that as-filed claim 17, which recited “a fusion cage”, was not rejected based on any of these references. Accordingly, the Applicant submits that independent claim 1, as amended, is patentable over these references, and withdrawal of the rejection of independent claim 1 based on these references is respectfully requested.

With regard to the Rinner reference, disclosed therein is a bone fusion mass container for promoting fusion between adjacent vertebrae. However, the Rinner reference fails to disclose or even suggest “an elongate member sized to span the intervertebral space”, and “a plurality of

bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height”, as now recited in independent claim 1. Indeed, the Rinner reference fails to disclose any type of “elongate member sized to span the intervertebral space”, much less an elongate member that is attached to adjacent vertebral bodies via “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies” to establish a select height of the intervertebral space and to maintain the select height. This distinction was apparently appreciated by the Examiner in that as-filed claim 24, which recited an elongate plate member engaged to adjacent vertebral bodies via bone screws, was not rejected based on the Rinner reference. Accordingly, the Applicant submits that independent claim 1, as amended, is patentable over the Rinner reference, and withdrawal of the rejection of independent claim 1 based on this reference is respectfully requested.

For at least these reasons, the Applicant submits that independent claim 1, as amended, is patentable over each of the cited patent references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 1. Claims 8-16 and 19-24 depend either directly or indirectly from independent claim 1, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 1. The Applicant notes that dependent claim 24 has been amended to improve its form in view of the amendments to independent base claim 1.

Additionally, new dependent claims 63-71 have been added to the subject application which depend either directly or indirectly from independent claim 1, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 1. New dependent claims 63-71 are supported, for example, by paragraphs [0015] and [0020], as-filed claims 2, 8, 9 and 15, and Figures 1-4.

Rewritten Independent Claim 2 and Dependent Claims 3-7 and 72-77

The Applicant has rewritten claim 2 in independent form and has amended claim 2 to recite, among other elements and features, an elongate member sized to span the intervertebral space, and “a plurality of bone anchors extending transversely from said elongate member and

into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height”, with “said spinal implant being rotatable relative to said elongate member about said longitudinal axis to align said second transverse dimension along said select height of the intervertebral space to thereby provide controlled compression of said spinal implant”. The amendments incorporated into rewritten independent claim 2 are supported, for example, by paragraph [0020], as-filed claims 8 and 15, and Figures 1-4.

With regard to the Rezaian, Day and Steffee references, none of these references disclose or even suggest a spinal implant including “a first pair of side surfaces spaced apart and arranged generally opposite one another to define a first transverse dimension sized for insertion within an intervertebral space between the adjacent vertebral bodies” and “a second pair of side surfaces spaced apart and arranged generally opposite one another to define a second transverse dimension greater than said first transverse dimension and corresponding to a select height of said intervertebral space”, and with “said spinal implant being rotatable relative to said elongate member about said longitudinal axis to align said second transverse dimension along said select height of the intervertebral space to thereby provide controlled compression of said spinal implant”, as recited in rewritten independent claim 2. This distinction was apparently appreciated by the Examiner in that as-filed claim 2 was not rejected based on any of these references. Accordingly, the Applicant submits that rewritten independent claim 2, as amended, is patentable over these references, and withdrawal of the rejection of rewritten independent claim 2 based on these references is respectfully requested.

With regard to the Rinner reference, as indicated above with regard to independent claim 1, this reference fails to disclose or even suggest “an elongate member sized to span the intervertebral space”, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height”, as recited in rewritten independent claim 2. Indeed, the Rinner reference fails to disclose any type of “elongate member sized to span the intervertebral space”, much less an elongate member that is attached to adjacent vertebral bodies via “a plurality of bone anchors extending transversely from said elongate

member and into engagement with the adjacent vertebral bodies” to establish a select height of the intervertebral space and to maintain the select height. This distinction was apparently appreciated by the Examiner in that as-filed claim 24, which recited an elongate plate member engaged to adjacent vertebral bodies via bone screws, was not rejected based on the Rinner reference. Accordingly, the Applicant submits that rewritten independent claim 2 is patentable over the Rinner reference, and withdrawal of the rejection of rewritten independent claim 2 based on this reference is respectfully requested.

With regard to the Crozet reference, this reference likewise fails to disclose or even suggest “an elongate member sized to span the intervertebral space”, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height”, as recited in rewritten independent claim 2. This distinction was apparently appreciated by the Examiner in that as-filed claim 24, which recited an elongate plate member engaged to adjacent vertebral bodies via bone screws, was not rejected based on the Crozet reference. Accordingly, the Applicant submits that rewritten independent claim 2 is patentable over the Crozet reference, and withdrawal of the rejection of rewritten independent claim 2 based on this reference is respectfully requested.

With regard to the Dixon reference, disclosed therein is a distractor/spreader instrument for distracting adjacent vertebrae, including distractor paddles 31 that are maintained in a vertical orientation relative to a flange 33 via insertion of the distractor paddles 31 within slots 32 defined by the flange 33. (See Figures 1 and 2). The flange 33 prevents rotation of the distractor paddles 31 to maintain the paddles in a vertical orientation within the disc space. (See Figures 1 and 2; paragraphs [0032] and [0041]). Accordingly, the Dixon reference fails to disclose or suggest a spinal implant that is “rotatable relative to said elongate member about said longitudinal axis to align said second transverse dimension along said select height of the intervertebral space to thereby provide controlled compression of said spinal implant”, as recited in rewritten independent claim 2. Indeed, the distractor paddles 31 are clearly not rotatable relative to the flange 33 due to positioning of the distractor paddles 31 within the slots 32. To the contrary, the flange 33 in fact prevents rotation of the distractor paddles 31 to maintain the

paddles in a vertical orientation. The Applicant also notes that even though the threaded bone dowel 53 appears to be rotatable relative to the flange 33, the threaded bone dowel 53 is cylindrical, and clearly does not include “a first pair of side surfaces spaced apart and arranged generally opposite one another to define a first transverse dimension” and “a second pair of side surfaces spaced apart and arranged generally opposite one another to define a second transverse dimension greater than said first transverse dimension” and corresponding to a select height of the intervertebral space. Instead, the transverse dimension of the dowel 53 is constant due to the uniform diameter of the dowel 53. Accordingly, the Applicant submits that rewritten independent claim 2 is patentable over the Dixon reference, and withdrawal of the rejection of rewritten independent claim 2 based on the Dixon reference is respectfully requested.

For at least these reasons, the Applicant submits that rewritten independent claim 2 is patentable over each of the cited patent references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 2. Claims 3-7 depend either directly or indirectly from rewritten independent claim 2, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 2.

Additionally, new dependent claims and 72-77 have been added to the subject application which depend either directly or indirectly from rewritten independent claim 2, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 2. New dependent claims 72-77 are supported, for example, by paragraphs [0015] and [0020], as-filed claims 8, 9, 15 and 17, and Figures 1-4.

Rewritten Independent Claim 17 and Dependent Claims 18 and 78-81

The Applicant has rewritten claim 17 in independent form and has amended claim 2 to recite, among other elements and features, an elongate member sized to span the intervertebral space, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height” as the spinal implant is transitioned from the first transverse dimension to the second transverse dimension to provide controlled compression of the spinal implant. The amendments incorporated into rewritten independent

claim 17 are supported, for example, by paragraphs [0020], as-filed claim 24, and Figures 1-4.

As discussed above with regard to independent claim 1, the Crozet, Rezaian, Day, Steffee and Dixon references fail to disclose or even suggest “a fusion cage” and “a bone growth promoting material positioned within said fusion cage to facilitate fusion with the adjacent vertebral bodies”, as recited in rewritten independent claim 17. This distinction was apparently appreciated by the Examiner in that as-filed claim 17 was not rejected based on any of these references. Accordingly, the Applicant submits that independent claim 17, as amended, is patentable over these references, and withdrawal of the rejection of independent claim 17 based on these references is respectfully requested.

With regard to the Rinner reference, as discussed above with regard to independent claim 1, the Rinner reference fails to disclose or even suggest “an elongate member sized to span the intervertebral space”, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height”, as recited in rewritten independent claim 17. This distinction was apparently appreciated by the Examiner in that as-filed claim 24, which recited an elongate plate member engaged to adjacent vertebral bodies via bone screws, was not rejected based on the Rinner reference. Accordingly, the Applicant submits that rewritten independent claim 17 is patentable over the Rinner reference, and withdrawal of the rejection of independent claim 17 based on this reference is respectfully requested.

For at least these reasons, the Applicant submits that rewritten independent claim 17 is patentable over each of the cited patent references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 17. Claim 18 depends from rewritten independent claim 17, and is submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 17.

Additionally, new dependent claims and 78-81 have been added to the subject application which depend either directly or indirectly from rewritten independent claim 17, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 17. New dependent claims 78-81 are supported, for example, by paragraph [0020], as-filed claims 2, 9, 15 and 24, and Figures 1-4.

Independent Claim 25 and Dependent Claims 28-31, 33, 34 and 82-85

The Applicant has amended independent claim 25 to recite, among other elements and features, “an intervertebral fusion device . . . including one or more openings configured to promote fusion with the adjacent vertebral bodies” and defining a primary transverse dimension and a secondary transverse dimension sized greater than the secondary transverse dimension and corresponding to a select height of the intervertebral space, an elongate member sized to span the intervertebral space, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height” as the device is rotated about the longitudinal axis to align the primary transverse dimension along the select height to provide controlled compression of said device. The amendments incorporated into independent claim 25 are supported, for example, by paragraphs [0015] and [0020], as-filed claims 17 and 24, and Figures 1-4.

As discussed above with regard to independent claim 1, the Crozet, Rezaian, Day, Steffee and Dixon references fail to disclose or even suggest “an intervertebral fusion device . . . including one or more openings configured to promote fusion with the adjacent vertebral bodies”, as now recited in independent claim 25. This distinction was apparently appreciated by the Examiner in that as-filed claim 17, which recited “a fusion cage”, was not rejected based on any of these references. Accordingly, the Applicant submits that independent claim 25, as amended, is patentable over these references, and withdrawal of the rejection of independent claim 25 based on these references is respectfully requested.

With regard to the Rinner reference, as discussed above with regard to independent claim 1, the Rinner reference fails to disclose or even suggest “an elongate member sized to span the intervertebral space”, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height”, as recited in independent claim 25 as now amended. This distinction was apparently appreciated by the Examiner in that as-filed claim 34, which recited an elongate plate member engaged to adjacent vertebral bodies via bone screws, was not rejected based on the Rinner reference. Accordingly, the Applicant submits that

independent claim 25 is patentable over the Rinner reference, and withdrawal of the rejection of independent claim 25 based on this reference is respectfully requested.

For at least these reasons, the Applicant submits that independent claim 25, as amended, is patentable over each of the cited patent references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 25. Claims 28-31, 33 and 34 depend either directly or indirectly from independent claim 25, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 25. The Applicant notes that dependent claim 34 has been amended to improve its form in view of the amendments to independent base claim 25.

Additionally, new dependent claims 82-85 have been added to the subject application which depend either directly or indirectly from independent claim 25, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 25. New dependent claims 82-85 are supported, for example, by paragraphs [0015], as-filed claims 2, 26 and 32, and Figures 1-4.

Rewritten Independent Claim 26 and Dependent Claims 27 and 86-88

The Applicant has rewritten claim 26 in independent form and has amended claim 26 to recite, among other elements and features, an elongate member sized to span the intervertebral space, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height”, with “said device being rotatable relative to said elongate member about said longitudinal axis to align said primary transverse dimension along said select height of the intervertebral space to thereby provide controlled compression of said device”. The amendments incorporated into rewritten independent claim 26 are supported, for example, by paragraph [0020], as-filed claims 8, 9 and 15, and Figures 1-4.

With regard to the Rezaian, Day and Steffee references, none of these references disclose or even suggest a device including “a pair of primary side surfaces spaced apart and arranged generally opposite one another to define a primary transverse dimension”, “a pair of secondary side surfaces spaced apart and arranged generally opposite one another to define a secondary

transverse dimension”, with “said primary transverse dimension sized greater than said secondary transverse dimension and corresponding to a select height of said intervertebral space”, and with “said device being rotatable relative to said elongate member about said longitudinal axis to align said primary transverse dimension along said select height of the intervertebral space” to provide controlled compression of the device, as recited in rewritten independent claim 26. This distinction was apparently appreciated by the Examiner in that as-filed claim 26 was not rejected based on any of these references. Accordingly, the Applicant submits that rewritten independent claim 26, as amended, is patentable over these references, and withdrawal of the rejection of rewritten independent claim 26 based on these references is respectfully requested.

With regard to the Rinner reference, as indicated above with regard to independent claim 1, this reference fails to disclose or even suggest “an elongate member sized to span the intervertebral space”, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height”, as recited in rewritten independent claim 26. This distinction was apparently appreciated by the Examiner in that as-filed claim 34, which recited an elongate plate member engaged to adjacent vertebral bodies via bone screws, was not rejected based on the Rinner reference. Accordingly, the Applicant submits that rewritten independent claim 26 is patentable over the Rinner reference, and withdrawal of the rejection of rewritten independent claim 26 based on this reference is respectfully requested.

With regard to the Crozet reference, this reference likewise fails to disclose or even suggest “an elongate member sized to span the intervertebral space”, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height”, as recited in rewritten independent claim 26. This distinction was apparently appreciated by the Examiner in that as-filed claim 34, which recited an elongate plate member engaged to adjacent vertebral bodies via bone screws, was not rejected based on the Crozet reference. Accordingly, the Applicant submits that rewritten independent claim 26 is

patentable over the Crozet reference, and withdrawal of the rejection of rewritten independent claim 26 based on this reference is respectfully requested.

With regard to the Dixon reference, as discussed above with regard to rewritten independent claim 2, the Dixon reference fails to disclose or suggest a spinal implant that is “rotatable relative to said elongate member about said longitudinal axis to align said primary transverse dimension along said select height of the intervertebral space to thereby provide controlled compression of said device”, as recited in rewritten independent claim 26. Indeed, the distractor paddles 31 are clearly not rotatable relative to the flange 33 due to positioning of the distractor paddles 31 within the slots 32. To the contrary, the flange 33 in fact prevents rotation of the distractor paddles 31 to maintain the paddles in a vertical orientation. The Applicant also notes that even though the threaded bone dowel 53 appears to be rotatable relative to the flange 33, the threaded bone dowel 53 is cylindrical, and clearly does not include “a pair of primary side surfaces spaced apart . . . to define a primary transverse dimension”, “a pair of secondary side surfaces spaced apart . . . to define a secondary transverse dimension”, with “said primary transverse dimension sized greater than said secondary transverse dimension and corresponding to a select height of said intervertebral space”. Instead, the transverse dimension of the dowel 53 is constant due to the uniform diameter of the dowel 53. Accordingly, the Applicant submits that rewritten independent claim 26 is patentable over the Dixon reference, and withdrawal of the rejection of rewritten independent claim 26 based on the Dixon reference is respectfully requested.

For at least these reasons, the Applicant submits that rewritten independent claim 26 is patentable over each of the cited patent references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 26. Claim 27 has been amended to depend from rewritten independent claim 26, and is submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 26.

Additionally, new dependent claims and 86-88 have been added to the subject application which depend either directly or indirectly from rewritten independent claim 26, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 26. New dependent claims 86-88 are supported, for example, by

paragraphs [0015] and [0020], as-filed claims 32 and 34, and Figures 1-4.

Rewritten Independent Claim 32 and Dependent Claims 89 and 90

The Applicant has rewritten claim 32 in independent form and has amended claim 32 to recite, among other elements and features, an elongate member sized to span the intervertebral space, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height” as the device is rotated about the longitudinal axis to align the primary transverse dimension along the select height to provide controlled compression of the device. The amendments incorporated into rewritten independent claim 32 are supported, for example, by paragraphs [0020], as-filed claims 29 and 34, and Figures 1-4.

As discussed above with regard to independent claim 1, the Crozet, Rezaian, Day, Steffee and Dixon references fail to disclose or even suggest “a fusion cage” and “a bone growth promoting material positioned within said fusion cage to facilitate fusion with the adjacent vertebral bodies”, as recited in rewritten independent claim 32. This distinction was apparently appreciated by the Examiner in that as-filed claim 32 was not rejected based on any of these references. Accordingly, the Applicant submits that rewritten independent claim 32 is patentable over these references, and withdrawal of the rejection of independent claim 32 based on these references is respectfully requested.

With regard to the Rinner reference, as discussed above with regard to independent claim 1, the Rinner reference fails to disclose or even suggest “an elongate member sized to span the intervertebral space”, and “a plurality of bone anchors extending transversely from said elongate member and into engagement with the adjacent vertebral bodies to establish said select height of the intervertebral space and to maintain said select height”, as recited in rewritten independent claim 32. This distinction was apparently appreciated by the Examiner in that as-filed claim 34, which recited an elongate plate member engaged to adjacent vertebral bodies via bone screws, was not rejected based on the Rinner reference. Accordingly, the Applicant submits that

rewritten independent claim 32 is patentable over the Rinner reference, and withdrawal of the rejection of independent claim 32 based on this reference is respectfully requested.

For at least these reasons, the Applicant submits that rewritten independent claim 32 is patentable over each of the cited patent references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 32. Additionally, new dependent claims 89 and 90 have been added to the subject application which depend either directly or indirectly from rewritten independent claim 32, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 32. New dependent claims 89 and 90 are supported, for example, by paragraph [0020], as-filed claims 26, 29 and 34, and Figures 1-4.

Independent Claim 35 and Dependent Claims 36-39

The Applicant has cancelled claims 35-39 without prejudice for possible submission in a continuing application.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 1-34 and 63-90.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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